

**HL7 SPL Working Group Process Communication Forum Telecon
Wednesday, February 08, 2012**

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov

SPL technical questions? Send to spl@fda.hhs.gov

UNII or SRS questions? Send to fda-srs@fda.hhs.gov

As of February 8, 2012: DailyMed has close to 34,000 SPL loaded.

Minutes:

Differences in the FDA stylesheet for PLR labels (201.56 and 201.57)

- Casing in patient information statement now has parts in upper & lower case, for these:
 - FDA-approved patient labeling
 - Medication Guide
- Bolded revision date
- FDA Stylesheet is currently not up-to-date – vendor is releasing fix soon.

Reminder: DailyMed stylesheet can differ from the FDA stylesheet

Managing multiple manufacturing statements in USPIs

- 2 labels for one product – with the same NDC code – the only difference on the labels is the Manufacturer. At the end of the label, after Section 17, it lists “Manufactured by,” “Manufactured for,” and “Distributed by.” The “Manufactured by” information is different in each label. Variability across attendees: One company keeps two different SPL, another keeps a single SPL.
- SPL reflects the content of label, and variation in the number of SPL may reflect Review Division decisions.

Inner Pack listing on NDC Directory – any movement to change the granularity of the listing?

Discussion continues inside the FDA on possible changes

D&B Portal

Look-up capability demo'd recently. Identification of who is accessing the system is required. Once a person signs in, able to search the same view of the data that FDA sees.

Potential disconnects being seen between address information on filings in US versus other companies.

More information/discussion planned for next ER/DL meeting (February 15)

Establishment – Product Code Validation Rule temporarily delayed in implementation**FYI**

- New training manual expected in the near future for Xforms. All of the materials are being revised, as the Xforms have been significantly modified over the last several versions.

Next meeting scheduled for February 22, 2012.